

REMARKS

Claims 1-9 and 56-59 are pending in the present application. No amendments have been made.

The present invention is directed to kits for delivery of restorative or viscous injectable materials into an intraosseous space. The kits comprise, *inter alia*, at least one cannula, at least one stylet insertable into the cannula and being movable therein, and at least one catheter having a high-porosity tip that is insertable into the cannula, wherein the porosity of the tip is about 60% to 90%.

Claims 1-9 and 56-59 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Reiley (U.S. Patent No. 7,081,122) in view of Motoda (WO 90/06150). The Applicants disagree and respectfully request withdrawal of the rejection.

In order for a rejection to be proper under 35 U.S.C. § 103, it must be established that the combination of prior art references contain all the elements of the claimed invention. Then, it must be demonstrated that (1) “the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process;” and (2) the prior art reveals “that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success.” *Medichem v. Rolabo*, 77 U.S.P.Q.2d (BNA) 1865 (Fed. Cir. 2006). *See also* M.P.E.P. §§ 2143, 2143.01.

The present invention is directed to the delivery of restorative or viscous materials into an intraosseous space. In contrast, Motoda is directed to catheters for use in the delicate interior walls of heart or blood vessels. Motoda at page 2, lines 25-27. Motoda describes that the porous tips are more pliable than non-porous tips, resulting in the prevention of heart or blood vessel damage. Motoda at page 2, lines 18-27. It has been asserted that “it would have been obvious . . . to modify the tip of the catheter of Reiley et al., as taught by Motoda, to prevent damage to the interior walls of the heart or blood vessels while releasing the substance.” Mar. 15, 2007 Office Action at 2-3. The Applicants assert that this statement fails to provide the motivation necessary to support a *prima facie* case of obviousness. Moreover, one of skill in the art would not have been motivated to modify Reiley in light of Motoda to make the claimed invention.

Motoda is directed to catheters for use in *heart or blood vessels*. In contrast, the present invention is directed to catheters for delivery of *restorative or viscous injectable materials* into an *intraosseous space*. There is no suggestion or motivation that the heart and blood vessel catheters described in Motoda are adaptable for use in the delivery of restorative or viscous injectable materials into intraosseous spaces. Moreover, the Examiner has not identified how Reiley would be modified in light of Motoda to produce any of the inventions recited in the pending dependent claims.

It is well established that “the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references.” *In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999). To establish a *prima facie* case of obviousness, it is essential that the Examiner identify a motivation, teaching, or suggestion, either in the references themselves or in the knowledge of one of skill in the art, to combine the cited art. *Id.* The Examiner has not identified *any* motivation, teaching, or suggestion to combine the cited references to produce the claimed invention. Instead, the Examiner asserts that the combination would be obvious “to prevent damage to the interior walls of the heart or blood vessels while releasing the substance.” But the present invention is not directed to releasing substances into heart or blood vessels—it is directed to the delivery of restorative or viscous injectable materials into an *intraosseous space*. The Examiner’s unsupported assertion is *not* what the MPEP requires.

The Examiner *must* find motivation in the references themselves or in some demonstrable expression of knowledge in the art. MPEP § 2144. If the Examiner chooses to take official notice of certain knowledge in the art in making the rejection, and that official notice is unsupported by documentary evidence, official notice “should only be taken by the examiner where the facts asserted to be well-known, or to be common knowledge in the art are capable of instant and unquestionable demonstration as being well-known. . . . [T]he notice of facts beyond the record which may be taken by the examiner must be ‘capable of such instant and unquestionable demonstration as to defy dispute.’” MPEP § 2144.03(A). An Examiner cannot rely on conclusory statements when dealing with particular combinations of prior art and specific claims. *Id.* The rationale upon which the Examiner relies must set forth. *Id.*

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REPLY FILED UNDER EXPEDITED
PROCEDURE PURSUANT TO
37 CFR § 1.116**

If the Examiner considers himself an expert in the field and elects to make of record his own declaration in support of the assertions, he may do so as provided for by MPEP § 2144.03(C) ("If the examiner is relying on personal knowledge to support the finding of what is known in the art, the examiner must provide an affidavit or declaration setting forth specific factual statements and explanation to support the finding."). In such case, the finality of the rejection must also be withdrawn so that Applicants can address the new citation. MPEP § 2144.03(B). Failing that, there is simply no evidence of the supposed motivation that is required. Because one of skill in the art would not have been motivated to modify the catheters of Reilly in view of the heart and blood vessel catheters of Motoda to produce the kits of the present invention for delivery of restorative or viscous injectable materials into an intraosseous space, the Applicants respectfully request withdrawal of the rejection.

Claim 3 stands rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Reiley in view of Motoda in view of Buscemi (U.S. Patent No. 5,500,013). In light of the comments above, this rejection is considered moot and the Applicants respectfully request that it be withdrawn.

The Applicants respectfully submit that the foregoing represents a *bona fide* attempt to advance the present case to allowance. Applicants submit that this application is now in condition for allowance. Accordingly, an indication of allowability and an early Notice of Allowance are respectfully requested. If the Examiner believes that a telephone conference would expedite prosecution of this application, please telephone the undersigned at 215-564-8918.

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